

Summary of the Drug Enforcement Administration's Proposed Rule for the Disposal of Controlled Substances

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This summary has been prepared for use by the Local Hazardous Waste Management Program in King County (WA) and its partners. It is based on an outline originally prepared by Stefanie Wnuck at the Product Stewardship Institute, who graciously allowed us to build on her work. PSI is acknowledged for allowing us to borrow its document; we accept responsibility for any errors or omissions in this resulting summary. – Dave Galvin, Margaret Shield, Taylor Watson and Alice Chapman, LHWMP, King County, Seattle WA [28 January 2013 version]

The Drug Enforcement Administration (“DEA”) has released proposed regulations (“the rule”) to implement the Secure and Responsible Drug Disposal Act of 2010 by expanding options to collect controlled substances from ultimate users for secure destruction.

Controlled substances (“CSs”) are drugs or other materials that, because of their potential for abuse, are closely regulated by the federal government; **“Schedule I”** CSs are illegal drugs such as cocaine or heroin that are not legal to possess or use; **“Schedule II through V”** CSs are legal pharmaceuticals; the rule addresses the collection and destruction of Schedule II – V CSs. In the controlled substance universe, **“registrants”** are those entities that are registered with DEA to handle controlled substance drugs from the point of manufacture through distribution to retail pharmacy sale. **“Reverse distributors”** are registrant companies authorized to accept unsold controlled substances from other registrants or law enforcement for purposes of return-for-credit or for destruction. **“Ultimate users”** are the customers who purchase the controlled substance drugs, to which they have been prescribed; they are non-registrants and are thus outside of the existing controlled substance system. DEA proposes slightly different requirements for certain **“Practitioners”** (i.e., retail pharmacies only) and **“Non-practitioners”** (i.e., manufacturers, distributors and reverse distributors) to collect CSs from ultimate users.

General background

Options proposed in the rule to collect controlled substances from ultimate users include:

1. **Take-back events** – conducted by law enforcement agencies only.
2. **Mail-back programs** – operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies or law enforcement agencies.
3. **Collection receptacle locations (i.e., permanent drop-off boxes)** – operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies or law enforcement agencies. Retail pharmacies may also operate collection receptacles at long-term care facilities (“LTCFs”).

The proposed regulations also reorganize and consolidate existing regulations on disposal, including the role of reverse distributors. Definitions and other details are amended in Parts 1301 – 1304 of Title 21 of the *Code of Federal Regulations* (“CFR”). A whole new **Part 1317**, labeled **“Disposal,”** is added. We reference specific sections of the proposed CFR citations throughout this summary.

Some other features of the rule:

- Controlled substances (Schedule II – V) can be accepted for disposal from:
 - An **ultimate user** (i.e., the patient to whom the drug is prescribed) [1317.30(b)(1)]; or

- **Individuals legally authorized to dispose of ultimate user decedent's property** (i.e., when a person dies, a person authorized to dispose of their property may return their drugs for disposal) [1307.30(b)(2)]; or
- **Long-term care facilities**, on behalf of an ultimate user who resides, or has resided, at the LTCF, only **via a collection receptacle maintained by a retail pharmacy** on the premises [1317.30(b)(3)]. (LTCFs include nursing homes, retirement homes, mental care or other facilities or institutions which provide extended health care to resident patients.)
- Controlled substances and non-controlled medicines can be **co-mingled** [1317.65(d), 1317.70(b) and 1317.75(b)].
- The rule is silent on the issue of **collection of loose pills** separated from their packaging (e.g., plastic pill bottles), therefore this practice is allowable.
- **CSs cannot be counted** separately or inventoried once collected.
- The rule is silent on methods to **protect confidentiality of patient information** on packaging (i.e., HIPAA protections), therefore best practices already in place at existing take-back programs can be utilized. Provisions prohibiting any inventorying of collected medicines also serve to protect patient information.
- Because some Schedule II CSs are likely to be collected, all containers of co-mingled, collected drugs must be handled at a **security level appropriate for Schedule II CSs** [1317.05(c)(1)(ii) and (c)(2)(ii)].
- All proposed collection methods are **voluntary**. (Nothing in the rule requires anyone to serve as a collector.)
- As a corollary, **no funding** mechanism is provided for CS disposal, collection or destruction.
- The proposed regulations are not intended to change established law enforcement agency procedures for handling, storage and transfer of CSs.

Collectors

- The following **existing registrants** can amend their registration with the DEA to become a collector of CSs from ultimate users (in addition, as noted below, law enforcement agencies are already authorized to handle CSs but are not included in the “collector” definition – see below for provisions for law enforcement programs):
 - **drug manufacturers,**
 - **drug distributors,**
 - **reverse distributors,**
 - **retail pharmacies** [1317.40(a)].
- To do so, a registrant needs to request a modification of its existing registration to be designated as a collector [1301.51].
- Collectors shall either **destroy the collected drugs on-site** [1317.05(c)(1)(i) and 1317.05(c)(2)(i)] **or transfer the drugs to either a distributor or reverse distributor** for final disposal in one of the following ways:
 - Pick-up at the authorized collection location by distributor [for pharmacy collectors this provision is stated in: 1317.05(c)(2)(iii); for all other authorized collectors, this provision is stated in: [1317.05(c)(2)(iv)]; or
 - Pick-up at the authorized collection location by reverse distributor [for pharmacy collectors this provision is stated in: 1317.05(a)(2); for all other authorized collectors, these provisions are stated in: 1317.05(b)(2)]; or

- Delivery by common or contract carrier to a reverse distributor [1317.04(a)(2) and 1317.05(b)(2)] or to a distributor [1317.05(c)(2)(iii) and 1317.05(c)(2)(iv)]; or
- For non-practitioners only (manufacturers, distributors or reverse distributors), prompt transportation by the authorized collector's "own means" following specific protocols to a reverse distributor or location for destruction [1317.05(b)(4), 1317.05(c)(2)(iv) and 1317.95(b)].
 - Detailed note: distributor registrants cannot use "freight forwarding facilities" to transfer collected CSs [1317.05(c)(2)(iv)].
 - Detailed note: transportation by a collector's own means shall include two authorized employees at all stages: loading, transport, unloading, handling, witnessed destruction [1317.95(b)]; same requirement for on-site destruction [1317.95(c)].
- Collectors must keep an inventory of all inner liners and mail-back packages and maintain records on use and destruction to account for disposal of CSs. However, the individual contents of a mail-back package or inner liner cannot be inventoried at any time.
- Collectors must dispose of drugs in the sealed mail-back packages or inner liners "promptly" – DEA does not give a specific time frame, saying the meaning of "prompt" is flexible and is not a specific time frame
 - Except that reverse distributors must destroy drugs within 14 days of receipt.
- Only a subset of existing registrants can be authorized to serve as collectors. Non-registrants such as government entities, HHW collection facilities, community centers, etc., cannot serve as collection locations.
- DEA's narrative notes the universe of potential collectors as follows:
 - Manufacturers – 522
 - Distributors – 828
 - Reverse Distributors – 60
 - Retail Pharmacies – 66,934
- The rule distinguishes between registrants who can apply to serve as "collectors" and law enforcement entities which are already authorized to handle CSs.

Collection by Law Enforcement Agencies

- Law enforcement can operate **take-back events**, **mail-back** or **collection receptacles** to collect CSs from ultimate users [1317.35(a)].
- Storage and record-keeping by law enforcement agencies should be consistent with the agencies' storage and record-keeping procedures for illicit (Schedule I) CSs (such as evidence) [1317.35(b) and (c)].
- At take-back events [1317.65(b)] and for mail-back programs [1317.70(f)], only a **law enforcement officer** (defined as a full-time government employee with authority to carry a firearm, make arrests and serve warrants [1317.02(a)]) can accept and handle ("maintain control and custody of") the CSs turned in by the ultimate users.
 - **This restriction is NOT spelled out in the rule for collection receptacles** hosted by law enforcement agencies.

- Law enforcement agencies can transport collected CSs to a destruction location as long as the transfer is done in a manner that prevents diversion [1317.35(d)]. Or the law enforcement agency can transfer collected CSs to a reverse distributor for destruction [1317.35(e)].
- As noted above, the proposed regulations are not intended to change established law enforcement agency procedures for handling, storage and transfer of CSs.

Take-back events

- Only **law enforcement agencies** can run take-back events, but other entities can partner or co-sponsor such events [1317.65(a)].
- Events can only be held by law enforcement agencies because take-back events do not have the same security as permanent collections and may be more vulnerable to diversion.
- The rule recommends that there should be at least one receptacle at take-back events to achieve optimal security [1317.65(c)].
- A law enforcement officer (as noted above) must oversee collection, handle and maintain control and custody of all CSs turned in [1317.65(b)].
- **No other person besides the ultimate user and the law enforcement officer may handle CSs** at any time during the event (e.g., community volunteers may not handle CSs) [1317.65(e)].

Mail-back

- **Law enforcement agencies** and **collectors who have on-site destruction capabilities** (e.g., reverse distributors) can run mail-back services [1317.70(a)].
- This requirement to destroy on-site does not apply to law enforcement agencies that conduct mail-back programs – law enforcement may continue to transfer collected CSs in mail-back packages to reverse distributors for destruction.
 - Only law enforcement officers (as noted above) can handle the mail-back packages received at a law enforcement location [1317.70(f)].
- Any other entity (e.g., retail pharmacy, government agency, sponsoring company) can **partner** with an authorized collector or law enforcement agency to make mail-back packages available to ultimate users [1317.70(c)].
- Example of a partnership:
 - An authorized collector with an on-site method of destruction (e.g., a DEA-registered reverse distributor) produces appropriate mail-back packages, and allows a third party business partner that is frequently accessed by the public (e.g., a retail pharmacy) to provide these packages to patronizing customers. The registered reverse distributor (NOT the participating retail pharmacy) would be responsible for operating the mail-back program, including recordkeeping and security, and must receive the mail-back packages directly as its registered location for on-site destruction.
- Proposed **specifications of mail-back package** [1317.70(c)(1-6)]:
 - Provided either at no cost or a fee;
 - Postage paid and pre-addressed to authorized mail-back location (i.e., collector's registered location with on-site method of destruction or to law enforcement agency's physical address);
 - Nondescript, tamper-evident, tear-resistant, water-proof, spill-proof and sealable;
 - Each package must have a unique ID number so that each package can be tracked;
 - Collector must keep inventory of mailers created and record the unique ID number of each package received;

- Each package must include instructions for the user that indicate process for mailing back the package, the permitted substances that can be sent, and related information;
 - No personal information from the ultimate user shall be required.
- While DEA is not proposing to require collectors to create and maintain an advance notification system (for ultimate users to notify the collector ahead of time when a package containing CSs is sent, as was done in the State of Maine’s pilot project), it is not prohibited by the regulations [1317.70(d)].
- DEA recognizes that proposed requirements may limit the number of companies authorized to conduct a mail-back program; however, it notes that a single authorized mail-back program would be capable of receiving packages from any location within the U.S.

Collection receptacles

- Registered **collectors** may maintain a collection receptacle at a DEA registered physical location. **Law enforcement agencies** may also maintain a collection receptacle at their registered locations.
 - Receptacles cannot be placed at non-registered locations such as libraries or community centers.
 - **Hospitals cannot be authorized collectors**, but a retail pharmacy that is co-located within a hospital (or a community clinic) may participate. DEA makes this distinction because it believes that hospitals do not have the same theft and loss prevention procedures as retail pharmacies.
- Proposed **specifications for collection receptacle** [1317.75(e)(1-3) and 1317.60]:
 - Permanent, “substantially-constructed,” securely locked outer container with removable inner liner;
 - Opening must be baffled or otherwise constructed so that contents can be added but not removed through it;
 - Opening must be capable of being locked when an authorized employee is not present (unless receptacle is located in a secured area of a LTCF);
 - Outer container must be securely fastened to a permanent structure such as a wall, floor, or immovable countertop;
 - Signage requirements must indicate that only Schedule II – V CSs and non-CSs are accepted (i.e., no illegal drugs – Schedule I – are accepted);
 - Inner liner must have permanent and unique identification number;
 - Inner liner must be waterproof, tamper-evident, tear-resistant, opaque and sealable, with the size clearly marked [1317.60].
 - Removal of inner liner shall be performed by or under the supervision of at least two authorized employees of the collector.

DEA notes in its narrative the reasons why it believes that retail pharmacies offer secure collection receptacle locations:

“In particular, DEA is proposing to authorize registered retail pharmacies to become collectors because such registrants are open to the public and have theft and loss prevention measures within the pharmacy processing area as well as outside the confines of the prescription processing and pick-up area, which easily lends itself to secure collection receptacle placement. Retail pharmacy personnel also routinely handle controlled substances intended for the ultimate user in a public setting while keeping such substances secure, and they have experience comingling controlled and non-controlled substances in the receipt and storage process. As public retail establishments, retail pharmacies generally have experience with the general public

as customers and routinely implement theft and loss prevention measures.” [Federal Register 77 (246): 75791]

Long-Term Care Facilities (LTCFs)

- Only authorized **retail pharmacy registrants** may operate a collection receptacle at a LTCF [1317.80(b)].
- LTCF staff must dispose of CSs on behalf of resident ultimate users only into an authorized collection receptacle [1317.80(a)].
- Such disposal must occur within 3 days after the discontinuation of use by the ultimate user.
- Only the authorized retail pharmacy may manage the collection receptacle at the LTCF, including removal of the inner liner, following protocols as noted above [1317.80(b)].
- Each physical location of a LTCF collection receptacle must be included in a retail pharmacy registrant’s registration [1317.80(c)].
- Without a collection receptacle, the LTCF is not permitted to dispose of a CS on behalf of an ultimate user. The ultimate user or persons lawfully entitled to dispose of the decedent’s property should dispose of the CS.

Role of reverse distributors and distributors

- The proposed rule modifies the definition of reverse distributor and modifies some requirements for reverse distributors.
- Reverse distributors can accept CSs that have been collected by law enforcement and other authorized collectors through collection receptacles and mail-back programs [1317.55(a)].
 - Not all law enforcement and collectors have resources to destroy CSs.
- Distributors can also accept CSs from authorized collectors through collection receptacles [1317.55(b)].
- Reverse distributors must destroy CSs no later than 14 days of pick-up or receipt.
 - The primary business activity of reverse distributors, unlike other registrants, is to acquire controlled substances for the purpose of destruction or return.
- Reverse distributors must keep records of receipt, storage, transfer and destruction of CS mail-back packages and inner liners, but cannot open or inventory the contents of packages or liners.

Disposal

- **Destruction** means that collected CSs must be rendered “**non-retrievable**” – to permanently alter any controlled substance’s physical and/or chemical state through irreversible means in order to render that controlled substance unavailable and unusable for all practical purposes [1317.90(a) and 1300.01(b)].
- The destruction standard is not prescribed otherwise. “DEA is proposing a standard that allows flexibility so long as the desired result is achieved, thus allowing for technological innovation and development.” [Federal Register 77 (246): 75804]
 - Examples of current technology that may achieve the non-retrievable standard are incineration and chemical digestion.
- **“Flushing and mixing controlled substances with coffee grounds or kitty litter ...do not meet the non-retrievable standard.”** [Federal Register 77 (246): 75803]
- **Destruction methods must meet all applicable federal, state, tribal, and local laws and regulations** [1317.90(a)].